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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,987

09/18/2006

Alexander Thomas Jacobs

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PATENT DIVISION

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EXAMINER

CARPENTER, WILLIAM R

ART UNIT

PAPER NUMBER

3767

NOTIFICATION DATE

DELIVERY MODE

07/25/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No. 10/598,987	Applicant(s) JACOBS ET AL.	
	Examiner WILLIAM CARPENTER	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/06/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is makes reference to a "means for driving" or "driving means" as part of the medication dispensing apparatus, appearing the invoke § 112 6th Paragraph. However, it is not clear from the specification what part of parts of the device Applicant considers to be the "driving means". Applicant briefly references the "driving means" in the specification (Page 2, Lines 10, 16, and 20), but fails to indicate any specific structure of reference numerals for what structure Applicant intends to be covered by the language "driving means". In order to properly invoke § 112 6th Paragraph the corresponding structure, material, or acts intended to be covered by the claim language must be adequately described in the specification. As Applicant does not adequately describe the "driving means" in the specification it is impossible for Examiner to properly identify the prior art which satisfies the same function and comprises the same supporting structure, materials, acts, or equivalents thereof. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

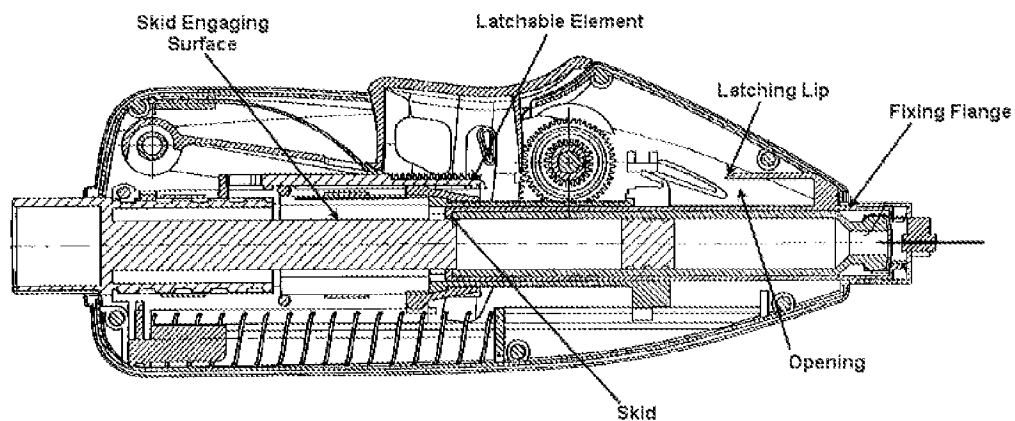
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-4, 6-8, and 10-11 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,599,272 (“Hjertman”).

Regarding Claim 1, Hjertman discloses a medication dispensing apparatus (200) comprising a housing (210), a drive member (271) within the housing a moveable in a distal direction (Figures 2E and 2F in series), and a fluid container (220) defining a medicine-filled reservoir with a movable piston (225) at one end and an outlet (222) at the other end, the piston engageable by the drive member to be advanced toward the outlet a distance equal to a distal movement of the drive member when the drive member is moved distally (Figures 2E and 2F in series). Hjertman further discloses a means for driving said drive member distally including a plunger element (260) and a gear set (241-243 in combination) shiftable with the plunger element. Hjertman further discloses a latching element (228) including a latching lip (see attached figure) and a skid (see attached figure). Hjertman discloses that the drive member includes an axially extending skid-engaging surface (see attached figure) along which the skid is slideable as the drive member passes distally during advancement, the skid-engaging surface

having an axial length and a proximal end such that the drive member along the axial length is structured and arranged with the skid so as to maintain the latching lip against a spring force in a first position (Figure 2D) free of the driving means during dose preparing and injecting prior to a final dose administration. Hjertman discloses that the skid-engaging surface shifts distally of the skid such that the skid passes beyond the proximal end upon administration of a final dose, whereby the latching lip is urged by the spring force from the first position to a second position (Figure 2F) to physically lock the driving means to prevent further dose preparing and injecting, wherein in the second position the latching lip engages a latchable element disposed on the plunger element (Figure 2F). It is noted that the “wherein” clause is held only to indicate functional language representative of an intended use of the device.



Regarding Claim 2, Hjertman discloses that the proximal end of the skid-engaging surface comprises a proximal end of the drive member (Figure 2F).

Regarding Claim 3, the skid of the device of Hjertman is interpreted to include not only the portion which contacts the skid-engaging surface but also the distally-extending

portion that connects the skid with the latching lip projection. As such, the skid of Hjertman is disposed distally of the latching lip (see attached figure).

Regarding Claim 4, Hjertman discloses that the skid comprises a blade shaped member that extends axially, and wherein the latching lip comprises a transversely extending flange (see attached figure).

Regarding Claim 6, Hjertman discloses that the latchable element comprises a ramped distal face over which the latching lip is cammable to reach a latching engagement with the latchable element (Figure 2F).

Regarding Claim 7, Hjertman discloses that the latching element is axially fixed to the housing by at least one flange fit into a slot provided in the housing (see attached figure).

Regarding Claim 8, Hjertman discloses that the spring force acting on the latching element comprises a resiliency of the latching element tending to return the latching lip to a neutral arrangement (Figures 2C and 2D in series).

Regarding Claim 10, Hjertman discloses that the skid-engaging surface is smooth (see attached figure).

Regarding Claim 11, Hjertman discloses that the latching lip comprises a rim along an opening (see attached figure) through which the latchable element extends to reach a latching engagement with the latching element (Figure 2F).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,599,272 ("Hjertman") as applied to Claim 8 above.

Regarding Claim 9, while Hjertman does illustrate the latching element to comprise a one-piece design, Hjertman fails to explicitly disclose that the element is a metal stamping. However, as Applicant has failed to disclose that forming the element of a metal stamping confers any advantage, particular purpose, or solution to a disclosed problem as compared to other alternative materials, it would have been obvious for one having ordinary skill in the art at the time the invention was made to form the latching element of the device of Hjertman of a metal composition since it has been held to be within the general skill of one having ordinary skill in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious

design choice. Compositions of metal, for example stainless steel, are art recognized for their strength, durability, and resiliency. Furthermore, Applicant's use of stamping to form the latching element fails to define or distinguish over any machining process which forms a one-piece design as the claim addresses an article of manufacture not a process.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 06 June 2008 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CARPENTER whose telephone number is (571)270-3637. The examiner can normally be reached on Monday through Thursday from 7:00AM-4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William Carpenter/
Examiner, Art Unit 3767
07/18/2008
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767

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